REMARKS

Claim 16 is amended herein to limit the urinary system diseases to those selected from the group consisting of prostatic hypertrophy, neurogenic bladder dysfunction disease, dysuria, pollakuria, night urination and urodynia. Support is found, for example, at page 3, lines 1-7.

No new matter is presented.

I. Response to Claim Rejections - 35 U.S.C. § 112

A. Written Description

Claims 1-10, 12-16 and 18 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. According to the Examiner, the new subgenus created by the amendments to the claims lacks support in the original disclosure. Specifically, the Examiner states that the new definitions for the variables are broader than "blazemarks" provided in the disclosure and one of ordinary skill in the art would not recognize that Applicants possessed the newly created subgenus based on the disclosure.

The Examiner goes on to state that the issue of whether the specification provides embodiments allowing use of the claimed invention without requiring undue experimentation in view of the highly unpredictable nature of inhibiting enzymes is particularly relevant to the instant case. The Examiner also states that the critical element is how broad the claims are to the level of unpredictability in the art and considers the test for enablement and the factors set froth at pages 3-4 of the Action.

Applicants traverse the rejection as improper.

Firs, Applicants submit that the Examiner fails to identify which of the amendments is not supported in the specification and which variables are considered to be broader than the disclosure in the specification. In the Amendment filed on February 20, 2009, it was noted that the claim amendments are supported by the original disclosure at pages 10, 15-17 and 20-24. Additionally, support for the amendments to the claims can be found, for example, in the original claims, namely claims 3, 4 and 8, and the examples of compounds in the original specification. Specifically the amendments to claim 1 regarding the definitions of the variables are supported by the disclosure as follows:

Ring A:	page 20, lines 25 and page 20, line 35 to page 31, line 2;
Ring B:	page 21, lines 27-31;
K:	page 21, lines 8-9;
Q:	page 22, lines 14-15;
M:	page 23, lines 29-32;
Ring D:	page 22, lines 24-28;
Ring E:	page 23, lines 20-21;
L:	page 23, lines 6-7;
Z:	page 24, lines 7-10;
t:	page 23, line 27.

Additionally, numerous examples of compounds within the scope of present claim 1 are provided in the specification. More specifically, the definition of the subgenus R^1 in $CONHSO_2R^1$ in the definition of Z is supported by the compounds of the examples.

On the other hand, the Examiner has not provided a reason as to why the exemplary compounds are not considered to be a representative number which supports the claimed subgenus. Thus, the Examiner has not met his initial burden of presenting evidence as to why a person skilled in the art would not recognize a description of the invention defined by the claims in the disclosure of the application. See MPEP § 2163.04.

Even further, the Examiner confuses the standard for written description and enablement and incorrectly applies the test for enablement. The written description requirement is separate and distinct from the enablement requirement and different standards apply. Thus, the Examiner's discussion of the factors for enablement with respect to the written description rejection are not considered to be relevant.

To the extent that the Examiner may have intended to make a lack of enablement rejection, Applicants submit that the rejection is without merit.

The Examiner takes the position that the claims are drawn to a large number of compounds for inhibiting enzymes, but the art of inhibiting enzymes is highly unpredictable. It is the Examiner's position that the IC50 value data provided for a single compound in the specification in view of the high unpredictability of the art of inhibiting enzymes is insufficient to enable the scope of the claims without specific guidance or correlations indicating how the structure affects the ability of the compound to perform the stated function. The Examiner

further indicates that an undue amount of experimentation would be required to synthesize and screen the billions of compounds within the scope of the claims.

However, from the discussion in the specification at pages 4-6, it can be seen that prior art compounds having some general structural similarity to the claimed compounds were known to have LPA antagonistic activity and/or EDG-2 antagonistic activity. Further, numerous examples of exemplary compounds and methods for synthesizing these compounds are provided in the specification.

Moreover, an assay for determining whether the compounds have EDG-2 antagonistic activity is also provided at pages 136-137. Such an assay is a standard method for screening compounds and the experimentation required for synthesizing and screening compounds within the scope of the invention is routine rather than undue.

More specifically, with regard to the Examiner's assertion that it is unclear whether compounds of the amended scope of the claims show utility is unclear, as described in the present specification, based on the fact that similar compounds disclosed in the prior application, US patent application number: 10/530,249, have EDG-2 antagonistic activity and the fact that the Declaration submitted on October 4, 2007 in the '249 application indicates pharmacological activity of compounds in Examples of the present application, the compounds in the present application which are limited to those having structures similar to compounds in the Examples have similar utility with the compounds described in the Declaration. A copy of the Declaration submitted on October 4, 2007 in the '249 application is attached for the Examiner's review and consideration in this application.

The Examiner also refers to Kubinyi in support of his position that the art is highly unpredictable, however the portion of Kubinyi provided and relied upon by the Examiner relates to multiple binding modes and certain aspects of inhibitor binding. Further, since the compounds in the present application are not enzyme inhibitors and are compounds antagonizing EDG-2 which is a LPA receptor, Applicants submit that it is inappropriate to reject the claims in the present application based on Kubinyi which relates to enzyme inhibitors. Thus, Kubinyi is not particularly relevant to the present case and/or is insufficient to rebut the discussion of the prior art in the present specification of compounds having some general structural similarity to the claimed compounds which were previously known to possess LPA and/or EDG-2 inhibitory activity.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112, 1st paragraph, for lack of written description.

B. Enablement

Claim 16 is rejected under 35 U.S.C. § 112, first paragraph, allegedly because the specification does not reasonably provide enablement for treatment of the claimed disorders.

The Examiner notes that the claims were amended to limit the method to treatment of urinary system disease, but the rejection is maintained allegedly because the specification provides minimal guidance and because of uncertainty in the art (as discussed above), with respect to the use of compounds of the entire genus of formula (1).

Applicants respectfully traverse in view of the comments above with respect to the discussion of the Examiner's position regarding a lack of enablement. Additionally, Applicants submit that the present specification provides *in vivo* data showing that a compound within the

scope of the present claims has an effect on urethral pressure, which can be reasonably correlated to the claimed method of treatment and other compounds within the scope of the present claims.

It is publicly known from US 7,288,558 that compounds having EDG-2 antagonistic activity are effective for treatment of urinary system diseases, especially pollakiuria and dysuria. Therefore, since the compounds in the present application have EDG-2 antagonistic activity as described above, it is clear that the compounds in the present application are effective for specific urinary system diseases recited in present claim 16 and that present invention enables the person skilled in the art to use the present invention.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112, 1st paragraph, for lack of enablement.

II. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

Susan J. Mack
Registration No. 30,951

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860
WASHINGTON DC SUGHRUE/265550
65565
CUSTOMER NUMBER

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